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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,332	06/21/2002	Kenneth J. Ruthschild	AMBER-06797	3619

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EXAMINER	
KATCHEVES, KONSTANTINA T	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,332	RUTHSCHILD ET AL.	
	Examiner	Art Unit	
	Konstantina Katcheves	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 21-68 are pending in the present application.

Response to Amendment

The rejections under 35 U.S.C. 102(e) over US Patent Number 6,306,628 and US Patent Number 6,303,337 are withdrawn in view of Applicant's argument that the present application is the national entry from International Application No. PCT/US00/23233 which claims the benefit of nonprovisional Application No. 09/382,950 now U.S. Patent 6,303,337, filed August 25, 1999, and Application No. 09/382,736 now U.S. Patent 6,306,628, filed August 25, 1999. Applicant's argument that these patents do not teach gel-free methods is noted but not persuasive because, for example, Figure 23a and 23b in each patent and the related description in the specification clearly teach gel-free quantitation of an N-terminal or c-terminal marker introduced into a nascent protein in accordance with the method of the invention.

Claims 21-68 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-16 of copending Application No. 10/174368 (Application '368). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Application '368 are drawn to a species of the instant claims such that the inventions of the instant claims are anticipated by Application '368.

Claims 21-68 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-43 of copending Application No. 10/339712 (Application '712) in view of Rothschild et al. (WO 01/14578 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention of the instant claims would have been obvious over the invention described in the claims of Application '712.

New Grounds of Rejection

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-29, 33-41, 44-53, 56-65 and 68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over either

claims 1-48 of U.S. Patent No. 6,303,337 ("'337") or claims 1-26 of U.S. Patent Number 6,306,628 ("'628") and both in view of Rothschild et al. (WO 01/14578 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The invention of the instant claims is drawn to a gel-free method of identifying a truncated protein comprising a) providing i) a misaminoacylated initiator tRNA molecule, said misaminoacylated initiator tRNA molecule comprising a first marker, and ii) a nucleic acid template encoding a protein, said protein comprising an affinity marker and a C-terminal marker, and b) introducing said misaminoacylated initiator tRNA to a translation system comprising said template under conditions such that a nascent protein is generated, said protein comprising said first marker, said affinity marker, and said C-terminal markers, and c) testing said nascent protein under gel-free conditions (Claims 21, 33, 45, and 57). The limitation of claims 23, 35, 47 and 59 comprise cell free or cellular translations systems wherein said systems are from various cell-types (claims 24, 25, 36, 37, 48, 49, 60 and 61). The cell-free system is a continuous flow or dialysis system (claims 27, 39, 51 and 63). The t-RNA is misaminoacylated by chemical or enzymatic means (claims 28, 40, 52 and 64).

Both '337 and '628 claim a method of detecting a truncated protein that involves amplification of a nucleic acid template with primers harboring N- and C- terminal markers, introduction of the amplified DNA in translation reaction and detecting the nascent protein. In addition they teach different types of nascent proteins such as recombinant gene products and enzymes, a cellular or cell-free translation system, various type of cellular translation systems such as tissue culture cells and primary

cells, various types of cell-free translation systems such as wheat germ extracts and insect cell lysates and a cell-free system that is a continuous flow or dialysis system with an incubation temperature between about 25C to 45C.

Both '337 and '628 teach methods comprising amplification of a nucleic acid template with primers harboring N- and C-terminal markers, introduction of the PCR amplified DNA and a biotin-misaminoacylated tRNA which reads on a misaminoacylated tRNA with a biotin marker into a translation system, isolation of nascent protein using streptavidin which is a biotin-binding ligand and detection of the nascent protein for truncations using measured ratios of the N- and C-terminal markers. The patents fail to claim a gel-free method.

Rothschild et al teaches a gel-free method of detecting a truncated protein that involves amplification of a nucleic acid template with primers harboring N- and C-terminal markers, introduction of the amplified DNA in translation reaction and detecting the nascent protein (page 1 18, lines 1-29 bridging page 1 19, lines 1-9). In addition they teach different types of nascent proteins such as recombinant gene products and enzymes (page 8, lines 6-10), a cellular or cell-free translation system, various type of cellular translation systems such as tissue culture cells and primary cells, various types of cell-free translation systems such as wheat germ extracts and insect cell lysates and a cell-free system that is a continuous flow or dialysis system with an incubation temperature between about 25C to 45C (page 10 lines 19-20, page 24, lines 28-29, page 25, lines 12-20, page 28 lines 12-26, page 148, lines 19-21). Rothschild et al teaches a gel-free method of detecting a truncated protein that involves amplification of

a nucleic acid template with primers harboring N- and C-terminal markers, introduction of the PCR amplified DNA and a biotin-lysyl-tRNxYs which reads on a misaminoacylated tRNA with a biotin marker into a translation system, isolation of nascent protein using streptavidin which is a biotin-binding ligand and detection of the nascent protein for truncations using measured ratios of the N- and C-terminal markers in a gel-free method (page 50, lines 26-30 bridging page 51 , lines 1-5, page 125-129, Example 25).

The invention of the instant claims would have been obvious to one of ordinary skill in the art at the time the invention was made in view of the claims of either '337 or '628. One of ordinary skill in the art would have been motivated to use a gel-free system of detection given the disclosure of Rothchild et al. specifically teaching detecting a protein under a gel-free system using the same method steps of either '337 or 628. Therefore, the invention as a whole is an obvious variation of the claims of '337 or '628.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
Examiner
Art Unit 1636